

§ 493.1

- 493.1717 Standard; Complaint investigations.
493.1719 Standard; Quality assurance review with staff.
493.1721 Standard; Quality assurance records.

Subpart Q—Inspection

- 493.1775 Condition: Inspection of laboratories issued a certificate of waiver.
493.1776 Condition: Inspection of laboratories issued a certificate for PPM procedures.
493.1777 Condition: Inspection of laboratories requesting or issued a certificate of compliance.
493.1780 Condition: Inspection of accredited and CLIA-exempt laboratories.

Subpart R—Enforcement Procedures

- 493.1800 Basis and scope.
493.1804 General considerations.
493.1806 Available sanctions: All laboratories.
493.1807 Additional sanctions: Laboratories that participate in Medicare.
493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.
493.1809 Limitation on Medicaid payment.
493.1810 Imposition and lifting of alternative sanctions.
493.1812 Action when deficiencies pose immediate jeopardy.
493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.
493.1816 Action when deficiencies are not at the condition level.
493.1820 Ensuring timely correction of deficiencies.
493.1826 Suspension of part of Medicare payments.
493.1828 Suspension of all Medicare payments.
493.1832 Directed plan of correction and directed portion of a plan of correction.
493.1834 Civil money penalty.
493.1836 State onsite monitoring.
493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.
493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.
493.1842 Cancellation of Medicare approval.
493.1844 Appeals procedures.
493.1846 Civil action.
493.1850 Laboratory registry.

Subpart S—[Reserved]

Subpart T—Consultations

- 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

42 CFR Ch. IV (10–1–96 Edition)

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

SOURCE: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§ 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under “laboratory” in § 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§ 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.